

**For discussion on
18 April 2016**

Legislative Council Panel on Health Services

Consultation Report on Regulation of Private Healthcare Facilities

PURPOSE

This paper briefs Members of the outcome of the Public Consultation on the Regulation of Private Healthcare Facilities (PHFs) and the way forward for revamping existing regulatory regime for PHFs.

BACKGROUND

2. Regulation of PHFs in Hong Kong is limited to a narrow set of premises drawn up in 1960s mainly covering private hospitals and non-profit-sharing medical clinics. The existing regulatory frameworks are outdated and have outlived their usefulness. Moreover, over the past few years, a number of medical incidents involving PHFs have attracted media attention on the service quality of PHFs. With a view to better regulating private healthcare services amid the evolving landscape of healthcare services, a Steering Committee on Review of Regulation of Private Healthcare Facilities (Steering Committee) was established in October 2012 to conduct a root-and-branch review on the regulation of PHFs.

3. A public consultation on the proposal to revamp the existing regulatory regime for PHFs was conducted between 15 December 2014 and 16 March 2015. The proposal was made with reference to the recommendation of the Steering Committee. Under the Public Consultation, we adopted a risk-based approach and identified three categories of PHFs to be regulated, namely, (a) hospitals, (b) facilities providing high-risk medical procedures in ambulatory setting and (c) facilities providing medical services under the management of incorporated bodies. We also proposed 19 regulatory aspects which, putting together, constitute the essential regulatory requirements under our proposed regulatory regime for PHFs. The 19 regulatory aspects proposed are summarised at **Annex A** for reference. In addition, we proposed that the

regulatory authority be vested with certain types of powers¹ to facilitate its enforcement. By strengthening regulation and enhancing standards, we hope that the revamped regulatory regime for PHFs could protect the rights of the consumers and could contribute to the sustainable development of Hong Kong's healthcare system.

4. During the consultation period, we launched a publicity campaign through various channels, including Announcement in the Public Interest, distribution of posters, leaflets, information booklets and Consultation Documents. A telephone survey was commissioned from January to June 2015 to facilitate collation and assessment of views on the proposals and issues related to the regulation of PHFs.

5. We attended the meeting of the Legislative Council Panel on Health Services (the Panel) on 15 December 2014 and its special meeting on 13 January 2015 to brief Members on the Consultation Document. We also listened to the views of deputations at another special meeting of the Panel on 17 February 2015. In addition to Legislative Council and District Council meetings, we also attended briefing sessions, including community forums organised by the Food and Health Bureau, briefings and seminars organised by various parties and stakeholders in the community to explain our proposals and listen to the views expressed by the community.

6. The public consultation period ended on 16 March 2015. We received 296 written submissions in total, including 238 from individuals and 58 from organisations. The public views received on the specific proposals under the proposed regulatory regime are analysed in the Consultation Report (executive summary at **Annex B**). The key findings are summarised in the following sections.

¹ Under our proposal, the regulatory authority/the Government should be empowered to –

- (a) issue and amend regulations/codes of practice;
- (b) inspect, collect and publish relevant information;
- (c) suspend a facility/service/use of equipment; and
- (d) appoint advisory committees, devise, review and update the scope and standards of regulation for facilities providing high-risk medical procedures.

PUBLIC VIEWS ON THE PROPOSED REGULATORY REGIME

(i) Solid Support for Strengthening Regulation of Private Healthcare Facilities

7. There was solid support for having a more modernised and comprehensive regulatory control for different categories of PHFs in Hong Kong. Respondents generally agreed that the current regulatory regime, which is limited to a narrow set of facilities drawn up decades ago, was not adequate amid the evolving landscape of private healthcare services. Some submissions urged for early implementation of a new regulatory regime for PHFs.

(ii) Strong Support for Proposed Scope of Regulation

8. There was strong support for adopting the risk-based approach and covering the three types of PHFs proposed under the revamped regulatory regime. Some submissions went further and suggested extending the scope of regulation to PHFs owned and operated solely by identical registered medical practitioners as well as medical laboratories. Besides, there were views that the names of the second and third categories of PHFs (i.e. “facilities providing high-risk medical procedures in ambulatory setting” and “facilities providing medical services under the management of incorporated bodies”) were too complex and should be simplified to avoid confusion and unnecessary disputes.

(iii) Support for the 19 Regulatory Aspects

9. The proposed 19 regulatory aspects were generally supported. The public views received on these 19 regulatory aspects, grouped under five broad categories of control, are summarised in ensuing paragraphs.

A. Corporate Governance

10. Views received supported the proposed regulatory aspects under the broad category of corporate governance. Some respondents suggested that in addition to covering hospitals as proposed, certain regulatory aspects should be applicable to non-hospital PHFs as well.

11. On the specific comments received, some pointed out that the qualifications and experience of the person to be appointed as a person-in-charge (PIC) should be clearly set out. Regarding the proposed complaints management system, there were views that in addition to hospitals, the proposed Independent Committee on Complaints against Private Hospitals (ICCPH)² should also handle complaints against the other two categories of PHFs. On having an information system connectable with the Electronic Health Record Sharing System, some submissions expressed their concerns on privacy issues and readiness of doctors in using such system. Some respondents also asked for details of the proposal to maintain accreditation status for hospitals, such as the type of accreditation body recognised and the timetable for implementing the mandatory requirement.

B. Standard of Facilities

12. Respondents were generally supportive of these regulatory aspects. One of the respondents opined that these proposals would help facilitate a territory-wide coordinated approach in contingency responses and preparedness for infectious disease outbreaks. Nonetheless, there were views that some non-hospital PHFs were located in commercial buildings through rental arrangement, which posed technical constraints on compliance with relevant requirements.

C. Clinical Quality

13. There was broad support for the proposed regulatory aspects under the category of clinical quality. There were views that the regulatory aspects which were proposed to be applicable to private hospitals should be extended to the other two categories of PHFs. Nevertheless, there were also views that the extension of such requirement to non-hospital PHFs, such as a full-fledged mechanism on sentinel events management, might be too onerous.

² We proposed to establish a two-tier complaints handling system to handle all complaints against private hospitals. The first-tier should be at the service delivery level at which private hospitals should manage complaints at source according to a standardised complaints handling mechanism as prescribed by the regulatory authority. The second-tier should handle unresolved cases according to a centralised and independent mechanism, through the ICCPH. For non-hospital PHFs, a simplified complaints handling mechanism was proposed.

D. Price Transparency

14. There was strong public support for regulating PHFs from the perspective of enhancing price transparency to enable consumers to make informed choices, which would in turn strengthen consumers' confidence in utilising private healthcare services. Most stakeholders supported the spirit of price transparency as an essential element in the revamped regulatory regime. Some went further in suggesting that there should be a measure in place under the regulatory regime to regulate/control price levels of private healthcare services.

15. Some respondents shared their views on the operational constraints facing the PHFs in this respect. For example, there was a suggestion that PHFs should only be required to publish a selected list of common items under their fee schedules due to resource consideration. Respondents also pointed out that hospitals might have little control or prior knowledge over the doctors' decision on medical treatments/procedures to be carried out, which would in turn affect the total charge. Thus, hospitals could only provide an "estimate", rather than "quotation", of the charges involved. Regarding the requirement for hospitals to disclose their historical bill sizes statistics, a respondent pointed out that not all hospitals possessed the necessary computer system/platform.

E. Sanctions

16. It was generally agreed that the existing sanctions under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343) were not commensurate with the scale of operation of and level of risks involved in PHFs, so there was little deterrent effect for non-compliance. Respondents supported imposing more severe sanctions on non-complying PHFs under the new regulatory regime. Furthermore, some submissions considered that the sanctions under our proposal remained inadequate and urged for more extensive and severe sanctions. On the other hand, there were concerns about casting the enforcement net too wide, and the extent of liabilities to be borne by officers like the PIC under different circumstances (e.g. malpractice of staff).

(iv) Broad Support for Conferring Powers on the Regulatory Authority

17. There was broad support for the regulatory authority/the Government to be vested with the powers stipulated in our proposal. There was also a view that the regulatory authority should be empowered to conduct public education and publicity programmes on the regulation of PHFs and rights of consumers.

WAY FORWARD

(i) Refinements to the Proposals

18. With broad support from the community, we will proceed to take forward the proposals along the general direction put forth in the Consultation Document. After carefully considering the views of all stakeholders, we propose to refine some of the specific proposals. These refinements include –

- (a) **names of PHFs:** we propose to simplify the names of the two categories of non-hospital PHFs under the proposed regulatory regime, from “facilities providing high-risk medical procedures in ambulatory setting” and “facilities providing medical services under the management of incorporated bodies” to “day procedure centres” and “clinics under the management of incorporated bodies” respectively. The changes proposed aim to allow the public to distinguish, in more layman terms, the differences in the nature of services provided by these two categories of PHFs;
- (b) **complaints handling system:** we propose to explore the feasibility of establishing an independent Committee on Complaints against Private Healthcare Facilities. The Committee would be empowered to look into complaints unresolved at service delivery level by private hospitals, as well as day procedure centres and clinics under the management of incorporated bodies. Cases considered substantiated might be followed up by relevant regulatory authorities;

- (c) **provision of budget estimate:** in response to the views received on the intrinsic uncertainties facing private hospitals in providing “quotations”, we propose to amend the regulatory aspect “Provision of Quotation” to “Provision of Budget Estimate”. By proposing such change, we hope to clarify the policy objective of requiring private hospitals to provide a plausible reference of the quantum of overall charge (rather than a definite “quote”) for the consideration of prospective patients; and
- (d) **sanctions:** having considered the views received, we consider that the offence provisions must be carefully crafted to deter serious non-compliance on the one hand, and to avoid placing unduly onerous responsibilities on relevant officers in PHFs on the other hand. We will critically review the scope and level of penalties of the proposed sanctions in the ensuing legislative exercise. Acts which may be considered offences include operating PHFs without licence, willfully obstructing public officers in performing duties, failing to comply with orders of suspension, etc. We will continue to engage stakeholders when deliberating relevant details under the new regulatory regime.

(ii) Implementation

19. To take forward the proposals set out in the Consultation Document as proposed to be refined in the manner set out in paragraph 18, we are taking steps to iron out details of the new regulatory regime in collaboration with various Government departments and stakeholders, with a view to introducing the relevant Bill to the Legislative Council in the 2016/17 legislative session. Cap. 165 and Cap. 343 will accordingly be repealed by the new legislation.

ADVICE SOUGHT

20. Members are invited to note the content of this paper.

**Food and Health Bureau
Department of Health
April 2016**

Nineteen Regulatory Aspects Proposed in the Public Consultation

	Regulatory Aspects	Private Hospitals	Facilities Providing High-Risk Medical Procedures in Ambulatory Setting	Facilities Providing Medical Services under the Management of Incorporated Bodies
A. Corporate Governance				
A1	Appointment of Person-in-charge	✓	✓	✓
A2	Establishing Medical Advisory Committee	✓	N/A	N/A
A3	Complaints Management System	✓	Simplified Mechanism	Simplified Mechanism
A4	Information System Connectable with Electronic Health Record Sharing System	✓	N/A	N/A
A5	Maintenance of Accreditation Status	✓	N/A	N/A
B. Standard of Facilities				
B6	Premises Management	✓	✓	✓
B7	Physical Conditions	✓	✓	✓
B8	Infection Control	✓	✓	✓
C. Clinical Quality				
C9	Service Delivery and Care Process	✓	✓	✓
C10	Resuscitation and Contingency	✓	✓	✓
C11	Standards Specific to Procedures Performed	✓	✓	N/A
C12	Credentialing of Visiting Doctors	✓	N/A	N/A
C13	Clinical Audit System	✓	N/A	N/A
C14	Sentinel Events Management	✓	Not now; could be considered in future	Not now; could be considered in future
D. Price Transparency				
D15	Provision of Fee Schedule	✓	✓	✓
D16	Provision of Quotation	✓	N/A	N/A
D17	Recognised Service Packages	Voluntary	Voluntary	Voluntary
D18	Disclosure of Historical Bill Sizes Statistics	✓	N/A	N/A
E. Sanctions				
E19	Sanctions	✓	✓	✓

Executive Summary of Consultation Report on Regulation of Private Healthcare Facilities

Chapter 1 The Public Consultation

The public consultation on Regulation of Private Healthcare Facilities (PHFs) was conducted between 15 December 2014 and 16 March 2015. We consulted the public on –

- (a) the three categories of PHFs proposed to be regulated and their respective definitions:
 - hospitals
 - facilities providing high-risk medical procedures in ambulatory setting
 - facilities providing medical services under the management of incorporated bodies;
- (b) the proposed 19 regulatory aspects and their applicability under the revamped regulatory regime; and
- (c) the proposed powers to be conferred on the regulatory authority.

2. During the consultation period, we launched a publicity campaign through various channels, including Announcement in the Public Interest, distribution of posters, leaflets, information booklets and Consultation Documents. A telephone survey was commissioned from January to June 2015 to facilitate collation and assessment of views on the proposals and issues related to the regulation of PHFs. In addition to Legislative Council and District Council meetings, we attended 25 briefing sessions, including community forums organized by the Food and Health Bureau, briefings and seminars organized by various parties and stakeholders in the community to explain our proposals and listen to the views expressed by the community. We received a total of 296 written submissions, comprising 238 from individuals and 58 from organizations.

Chapter 2 Public Views on Private Healthcare Facilities to be Regulated

Proposed Regulatory Regime

3. There was solid support for our proposal of having a more modernized and comprehensive regulatory control for different categories of PHFs in Hong Kong. Respondents generally agreed that the current regulatory regime, which is limited to a narrow set of facilities drawn up decades ago mainly covering private hospitals and non-profit-sharing medical clinics, was not adequate amid the evolving landscape of private healthcare services. Noting that the Government was also consulting the public on the Voluntary Health Insurance Scheme in parallel, some respondents urged for early implementation of a new regulatory regime for PHFs.

Classification of PHFs

4. There was strong support for covering the three types of PHFs proposed under the revamped regulatory regime. There were views pointing out that the names of the second and third categories of PHFs (i.e. “facilities providing high-risk medical procedures in ambulatory setting” and “facilities providing medical services under the management of incorporated bodies”) were too complex and should be simplified to avoid confusion and unnecessary disputes. It was also suggested that the scope and definitions of PHFs to be regulated should be reviewed regularly.

5. Regarding the approach in determining the types of PHFs to be regulated, there was solid support for adopting a risk-based approach by assessing the risk of procedures and operational risks involved in each type of PHFs. There was a view that other contributing factors (e.g. the technology employed for procedures) should also be considered in risk assessment for delineating high-risk procedures. A few respondents considered that the scope of regulation should go further to cover PHFs owned, managed, operated and serviced solely by identical registered medical practitioners, or even medical laboratories.

Chapter 3

Public Views on Proposed Requirements on Corporate Governance

(A1) Appointment of Person-in-charge

(A2) Establishment of Medical Advisory Committee

6. There was support for the proposals to regulate the appointment of person-in-charge (PIC) for all PHFs by clearly setting out the responsibilities of a PIC, and to mandate the establishment of Medical Advisory Committee for private hospitals. Some respondents even suggested that the requirement to establish Medical Advisory Committee should be extended to non-hospital PHFs. Some views pointed out that the qualifications and experience of the person to be appointed as a PIC should be clearly set out.

(A3) Complaints Management System

7. There was overwhelming support for the Government to set up a complaints management system. Some respondents stressed the importance of independence and objectivity of the proposed system, and suggestions on various fronts were made in this regard. There were suggestions that in addition to hospitals, complaints against the other two categories of PHFs to be regulated should also be reviewed by the proposed Independent Committee on Complaints against Private Hospitals.

(A4) Establishment of an Information System Connectable with the Electronic Health Record Sharing System

8. The proposal to require hospitals to establish an information system connectable with the Electronic Health Record Sharing System was generally supported. Respondents pointed out that the proposal would provide the necessary framework for transition of patients between different levels of care and between the private/ public sector, and that the proposal should also cover other categories of PHFs (in addition to hospitals) in the long term. On the other hand, some respondents expressed their concerns on privacy issues and the readiness of doctors in using such system.

(A5) Maintenance of Hospital Accreditation Status

9. The proposal for hospitals to maintain a hospital accreditation status was supported. A respondent pointed out that detailed information on the type of accreditation body that was acceptable by the regulatory authority should be specified. Another respondent agreed that in the long term, hospital accreditation should be made a mandatory requirement for private hospitals, and suggested that the regulatory authority should set a timetable for its implementation.

Chapter 4

Public Views on Proposed Requirements on Standard of Facilities

(B6) Premises Management

(B7) Physical Conditions

(B8) Infection Control

10. Responses received from respondents were generally supportive regarding the regulatory aspects on standard of facilities. One of the respondents opined that these proposals would help facilitate a territory-wide coordinated approach in contingency responses and preparedness for infectious disease outbreaks. Some submissions pointed out that some non-hospital PHFs were located in commercial buildings through rental arrangement, which posed technical constraints on compliance with relevant requirements.

Chapter 5

Public Views on Proposed Requirements on Clinical Quality

(C9) Service Delivery and Care Process

(C10) Resuscitation and Contingency

(C11) Standards Specific to Procedures Performed

11. Among the comments received, the three regulatory aspects of “Service Delivery and Care Process”, “Resuscitation and Contingency” and “Standards Specific to Procedures Performed” proposed were considered important elements for safeguarding the safety of patients and ensuring provision of quality healthcare services. A respondent suggested that for the additional standards for selected procedures, reviews should be conducted periodically.

(C12) Credentialing of Visiting Doctors

12. The proposed requirement on credentialing of visiting doctors by private hospitals was supported. A respondent stressed the importance of the private hospitals having in place an appropriate human resources policy. There was also a view that the credentialing of doctors should not only be limited to hospitals, but should also be extended to facilities providing high-risk medical procedures in ambulatory setting.

(C13) Establishment of Clinical Audit System

13. There was broad support for the proposed clinical audit system for private hospitals. Similar to the credentialing of visiting doctors above, some respondents opined that the establishment of clinical audit system should also be applied to non-hospital PHFs.

(C14) Sentinel Events Management

14. There were views that citizens should have the right to be informed when sentinel events occurred, and that the experience of the Hospital Authority on sentinel events reporting could be a useful reference for private hospitals to promote continuous quality improvement. Some respondents opined that this regulatory aspect should be applicable not only to hospitals but also facilities providing high-risk medical procedures in ambulatory setting. On the other hand, there were concerns that a full-fledged mechanism might be too onerous on non-hospital PHFs.

15. Issues pertaining to privacy have also been raised regarding this regulatory aspect. It was pointed out that the mishandling of personal data and excessive disclosure of relevant information in reporting/ investigation of the sentinel events/ medical incidents could be highly intrusive upon the privacy of the affected individuals. Therefore, it was suggested that due regard must be given to protect the personal data of the individuals affected. On this issue, another respondent stressed the importance of legal privilege of information produced during an investigation and root cause analysis, and pointed out that legal protection of confidentiality would encourage open discussion among healthcare professionals to facilitate improvement.

Chapter 6

Public Views on Proposed Requirements on Price Transparency

Support for Enhancing Price Transparency

16. The views received reflected strong public support for regulating PHFs from the perspective of enhancing price transparency to enable consumers to be better informed, which would in turn strengthen consumers' confidence in utilizing private healthcare services. Most stakeholders shared our view and supported the spirit of price transparency as an essential element in the revamped regulatory regime. Specifically, there were views expressing concerns over the existing inadequacy in price transparency in PHFs. There were also concerns that no measure had been proposed under the new regulatory regime to regulate/ control price levels of private healthcare services.

(D15) Provision of Fee Schedule

17. There was solid support for requiring PHFs to make available fee schedules to the public. There was a suggestion that due to resource consideration, PHFs should only be required to publish a selected list of common items under their fee schedules. Separately, it was suggested that measures should be put in place to monitor the changes in service fees of PHFs in order to prevent a drastic increase of private healthcare service fees.

(D16) Provision of Quotation

18. There was clear support for this regulatory aspect. There was a view that in addition to hospitals, the other two categories of PHFs should provide quotations to customers/ patients as well.

19. While supportive of the proposal on the provision of quotations, there were some concerns expressed on the operational constraints of meeting this requirement, in that hospitals might have little control or prior knowledge over the doctors' decision on medical treatments/ procedures to be carried out, which would in turn affect the patient's length of stay, duration of operations and procedures, number and type of investigations to be conducted, and use of consumables, etc. Therefore, unlike the unit cost of chargeable items (e.g. daily room charge) that could be accurately quoted, it was suggested that any estimate of the total charge likely to be incurred should be called "estimate" rather than "quotation" in view of the uncertainties that could arise during the whole medical journey from admission to discharge.

(D17) Provision of Recognized Service Packages

20. It was generally agreed that recognized service packages (RSPs), to be provided voluntarily by PHFs under our proposal, were an effective way to enhance price transparency of private healthcare services. Several views considered that this regulatory aspect should be made compulsory, otherwise its effectiveness would be significantly hindered in providing sufficient protection to patients/ consumers. Some respondents supported the idea of package pricing such that consumers/ patients could have better financial planning before engaging private healthcare services.

21. It was suggested that there should be an implementation timetable for rolling out a specific number of RSPs to be provided by PHFs. It was also pointed out that PHFs should be required to notify the regulatory authority and make the information available at the common electronic platform provided by the regulatory authority whenever there was any update on the provision of RSPs and their prices.

(D18) Disclosure of Historical Bill Sizes Statistics

22. There was strong support for the proposal of requiring hospitals to publish key historical statistics on their actual bill sizes for common treatments/ procedures as prescribed by the regulatory authority. One respondent suggested that all three categories of PHFs under regulation should provide historical bill sizes statistics. Another respondent pointed out that while some private hospitals had already published such statistics on their websites, some other hospitals might not have the necessary computer system/ platform and might take time and resources to implement this aspect.

Chapter 7

Public Views on Proposed Sanctions

(E19) Sanctions

23. It was generally agreed that the existing sanctions under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics

Ordinance (Cap. 343) were not commensurate with the scale of operation of and level of risks involved in PHFs, so there was little deterrent effect for non-compliance. The proposal to impose more severe sanctions on non-complying PHFs under the new regulatory regime was supported. Some submissions suggested the Government to consider introducing sanctions that were more extensive and severe than those under our proposal.

24. Respondents were generally supportive of introducing sanctions which were commensurate with certain benchmarks (e.g. risk levels involved) for the three categories of PHFs. There were also concerns about casting the enforcement net too wide, and the extent of liabilities to be borne by officers like the PIC under different circumstances (e.g. malpractice of staff).

Chapter 8

Public Views on Proposed Powers of the Regulatory Authority

25. There was broad support for the regulatory authority/ the Government to be vested with powers stipulated under our proposal. There were views opining that the regulatory authority should take proactive actions in administering and supervising PHFs' compliance with the regulatory aspects proposed. It was also suggested that the regulatory authority should be empowered to conduct public education and publicity programmes on the regulation of PHFs and rights of consumers.

Chapter 9

Conclusion and Way Forward

26. With broad support from the community, we will proceed to take forward the proposals along the general direction set out in the Consultation Document. We propose to refine some specific proposals taking into account the views received from the public and relevant stakeholders, including simplifying the names of the second and third categories of PHFs to be regulated (from “facilities providing high-risk medical procedures in ambulatory setting” and “facilities providing medical services under the management of incorporated bodies” to “day procedure centres” and “clinics under the management of incorporated bodies” respectively); exploring the feasibility of establishing an independent Committee on Complaints against Private Healthcare Facilities, which would be empowered to look into complaints unresolved against all three categories of PHFs at service delivery level; changing the name of the regulatory aspect “Provision of Quotation” to “Provision of Budget Estimate”; and critically reviewing the scope and level of penalties of the proposed sanctions in the ensuing legislative exercise. Other measures will also be stipulated in the law to tackle with breaches of other regulatory requirements including the codes of practice, such as suspension of service or even cancellation of licence.

27. To take forward the proposals set out in the Consultation Document, we are taking steps to iron out details of the new regulatory regime in collaboration with various Government departments and stakeholders, with a view to introducing the relevant Bill to the Legislative Council in the 2016/17 legislative session.